

### **REMARKS**

This Amendment is being filed in response to the Office Action dated April 16, 2008. Claims 12-22 are currently pending in the application, all of which stand rejected. Of these, claims 12 and 16 are independent. By this Amendment, claims 12 and 16 are amended to better clarify the invention and not to narrow or limit the scope of the claim in any way. Support for the amendments can be found at least in paragraphs [009] and [0027] and FIG. 5. As shown in FIG. 5, the dressing is provided without any artificial limb being attached thereto. Accordingly, one of ordinary skill reading the specification as originally filed and further in light of FIG. 5 would understand that the application is directed to a non-weight bearing dressing. No new matter has been added. Accordingly, claims 12-22 remain pending in this application and are in condition for allowance. Applicant respectfully requests reconsideration in light of the amendments and comments set forth herein.

### **Rejection under 35 U.S.C. §103**

Claims 12-15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,571,208 to Caspers ("Caspers") in view of U.S. Patent No. 5,830,237 to Kania ("Kania") and U.S. Patent No. 6,368,357 to Schon et al. ("Schon") and Application Publication No. 2003/0114783 to Vanden ("Vanden"). Claims 16 and 18-22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Caspers in view of Kania and Vanden. Dependent claim 17 is rejected under 35 U.S.C. §103(a) as being unpatentable over Caspers in view of Kania and Vanden further in view of Schon.

Applicants respectfully submit that the references, either taken alone or in combination, fail to teach or suggest "providing a non-weight bearing post-operative protection to a limb within ten days from amputation of a limb" or "compressing and containing the post-operative

limb by applying a thermo plastic gel liner on the post-operative limb” as recited in independent claims 12 and 16 as amended herein.

*None of the references teach or suggest “providing a non-weight bearing post-operative protection”*

Applicants respectfully submit that all the references, Caspers, Kania, Schon and Vanden are directed toward weight bearing devices and thus teach away from the invention as claimed. Casper describes the liner and sleeve for “donning over a residual limb and fitting within the socket of an artificial limb.” (Abstract; Col. 3, lines 54-55). Casper continues to describe the drawbacks associated with artificial limbs and their socket liners available, and further describes its liner as being used for artificial limbs. As one of ordinary skill would understand, an artificial limb is a weight bearing device. In fact, Casper explicitly states that its device is directed toward a “weight bearing” device. ( Col. 3, line 46; col. 6, line 62; col. 7, lines 1-5; col. 9, lines 9). Accordingly, Casper does not teach or suggest “providing a non-weight bearing post-operative protection” but rather, teaches away from providing such a device.

Kania is also directed to a gel for weight bearing devices, and more specifically for providing cushioning between a limb and a prosthetic device. Kania describes the use of gels for minimizing the discomfort of “a prosthetic device, such as an artificial arm or leg.” (Col. 1, lines 18-20) and to provide cushioning “between the residuum and a prosthetic device socket.” (Col. 3, lines 56-59; col. 4, lines 1-2; col. 6, line 67 to col. 7, line 1). Accordingly, Kania also fails to teach or suggest, and in fact, teaches away from, a “non-weight bearing” device as claimed.

Likewise, Schon is directed to a weight bearing device. Schon provides that its system “could also be used with an attachable pylon and foot to promote symmetrical body image and the psychological well-being of the amputee, and will also permit early partial weight bearing.” (Col. 2, lines 40-43) Schon also states “[t]he use of the therapeutic device 20 of the present

invention in conjunction with a pylon 60 and foot 62 immediately after surgery helps the amputee develop balance and a tolerance to weight bearing and prevents contractures and loss of muscle strength.” (Col. 6, lines 54-59). Accordingly, Schon also fails to teach or suggest, and in fact, teaches away from, a “non-weight bearing” device as claimed.

Vanden is also directed to a weight bearing device and thus also teaches away from the invention as claimed. Vanden is directed to an orthopedic device having a clam shell having an implement attached thereto. As one of ordinary skill in the art would understand, such a device is a weight bearing device. Furthermore, Vanden is directed to addressing hand and wrist dysfunctions, and not a “recently amputated residual limb.” Thus, a non-weight bearing device lacking an implement would defeat the objectives of Vanden and render it unsuitable for its purpose. Thus it would not have been obvious to modify Vanden to provide a non-weight bearing device, and Vanden teaches away from the invention as claimed.

*None of the references teach or suggest “within ten days from amputation” or “compressing and containing the recently amputated residual limb by applying a thermo plastic gel liner on the recently amputated residual limb”*

Casper, Kania, Schon and Vanden further fail to teach or suggest providing a protection device “within ten days from amputation” and “compressing and containing the recently amputated residual limb by applying a thermo plastic gel liner on the recently amputated residual limb” as recited in claims 12 and 16 as amended herein.

Casper, Kania and Vanden are not directed to a device provided within ten days from amputations as claimed, and further fail to teach or suggest the step of “compressing and containing” a limb by applying a thermoplastic gel liner. In fact, Casper, Kania and Vanden are not directed to “recently amputated residual limb” or to treating a residual limb within ten days of amputation. As one of ordinary skill in the art would appreciate, a weight bearing device

would not be provided on a recently amputated residual limb. To do so would likely apply too much pressure on the residual limb and would not “compress and contain” the limb as claimed. Casper, Kania and Vanden are no exception, and one of ordinary skill in the art would understand that the devices described therein would not be suitable for a recently amputated residual limb within ten days from amputation. Modifying Casper, Kania and Vanden to provide such a method and device would render Casper, Kania and Vanden unsuitable for their intended purposes. Accordingly, not only do Casper, Kania and Vanden fail to teach or suggest “within ten days from amputation” and “compressing and containing the recently amputated residual limb by applying a thermo plastic gel liner on the recently amputated residual limb,” but rather, teach away from such claim limitations.

Schon is directed to post-operation treatment and teaches away from the invention as claimed, and more specifically, “compressing and containing the recently amputated residual limb by applying a thermo plastic gel liner on the recently amputated residual limb.” Schon provides:

Notably, because of its unique configuration, the therapeutic device 20 of the present invention **need not be custom molded to a particular user, but rather may be used to fit amputees of varying sizes**. Once the residual limb 10 is placed within the shell 22 and the second shell portion 26 moved to envelop the limb 10, the fastening means 30 may be adjusted as needed to secure the shell 22 in a closed position about the circumference of the limb. **The bladders 40 may then be suitably inflated to essentially encompass the entire circumferential surface of the residual limb 10 and provide a comfortable, soft interface.**

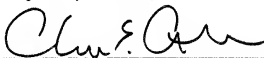
(Col. 5, line 59 to col. 6, line 2). Accordingly, Schon fails to teach or suggest “applying a thermo plastic gel liner on the recently amputated residual limb” for “compressing and containing the recently amputated residual limb.” In contrast, Schon teaches **not** to provide custom molding the orthotic and instead, stating that it is beneficial to inflate bladders to

encompass the surface of the residual limb. Accordingly, Schon teaches away from the invention as claimed. Furthermore, Schon, which teaches away from a custom molded device, teaches away from the invention, which provides the steps of wrapping the residual limb with gauze to create a custom made cast as claimed.

At least for the reasons set forth above, Applicants respectfully maintain that independent claims 12 and 16 are patentable over Caspers in view of Kania, Vanden and Schon, either taken alone or in any combination thereof. In the interest of brevity, Applicants also respectfully maintain that dependent claims 13-15 and 17-22 are also patentable over Caspers in view of Kania, Vanden and Schon, and the merits of the rejections will not be addressed in detail herein.

No fee other than the three-month extension of time and the fee for the Request for Continued Examination submitted herewith is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, the Examiner is hereby authorized to charge the amount of such fee to Deposit Account No. 19-4709.

Respectfully submitted,



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